510(k) Summary
Special 510K
Precision Medical, Inc. Easy Go Aspirator.

APR 2 5 2014

Submitter Information

Submitter	Precision Medical, Inc. 300 Held Drive Northampton, Pa. 18067
Facility Registration #	2523148
Contact	James Parker Quality Assurance Manager
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Preparation Date:	January 20, 2014

Device Name

Proprietary Name:	Easy Go Vac
Model number	PM66
Common Name:	Aspirator
Classification Name:	Pump, Portable,Aspiration
Classification Product Code:	BTA
Regulation number:	878.4780
Regulatory Status	Class II

Predicate Device Equivalence

Precision Medical, Inc. is claiming substantial equivalence to the Precision Medical Inc
Portable aspirator
Model # pm 65
510Knumber K971749
Manufactured by:
Precision Medical Inc.
300 Held Drive
Northampton Pa 18067

Device Descriptions ;

Predicate Device (PM65)

Small DC motor that powers a suction pump monitored by a gauge, vacuum is set by the care provider up to 21 inches of mercury. Uses a internal12 volt lead acid battery, with external charger/power supply.

New Device PM66 (3 models)

General description;
Small DC motor that powers a suction pump monitored by a gauge, vacuum is set by the care provider up to 21 inches of mercury. Uses an internal battery, with internal charger/power supply, on two models, and AC only on the third model.

PM66LI model
Small DC motor that powers a suction pump monitored by a gauge, vacuum is set by the care provider up to 21 inches of mercury. Uses an internal Lithium battery, with internal charger/power supply. (charge status indicator along with a battery level indicator, disposable or reusable waste container)

PM66AC
Small DC motor that powers a suction pump monitored by a gauge, vacuum is set by the care provider up to 21 inches of mercury. Uses AC 100-240 volts power only.

PM66S
Small DC motor that powers a suction pump monitored by a gauge, vacuum is set by the care provider up to 21 inches of mercury. Uses an internal lead acid battery, with internal charger/power supply. (charge status indicator along with a battery level indicator, disposable or reusable waste container)

Differences from the new devices to the Predicate device

- Battery charger is internal on new devices for PM66LI and PM66S
- Lithium battery on the PM66LI model
- AC only Model
- Addition of the charge indicator
- Addition of the battery level indicator
- Choice of reusable or disposable waste container

Conclusion:

The new devices are adding features that enhance the operation,
The lithium battery extends battery run time.
The AC model simplifies the device, for operators that do not need a portable device but want a simple small, easy to use device.
The lead acid battery model is the same as the predicate, with the added features of optional containers, a battery status indicator and the charge indicator.

The safety and effectiveness of the new devices compared to the predicate are substantially equivalent, with added features that ease, and enhance the operation.

Intended Use

The Easy Go Aspirator provides a portable, AC/DC powered medical vacuum source. It is intended for use in the homecare / health care environments.

Applied Standards;

ISO 15223-1:2012
BS EN 1041:2008
EN ISO 10079-1:2009
IEC 60601-1:2005 ed3.1 Consol. with am1
IEC 60601-1-2:2007
IEC 60601-1-6:2007
IEC 60601-1-11:2010
EN ISO 14971:2012
ISO 13485:2012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 25, 2014

Precision Medical Incorporated
Mr. James Parker
Quality Assurance Manager
300 Held Drive
Northampton, Pennsylvania 18067

Re: K140179
Trade/Device Name: Easy Go Vac
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: BTA
Dated: April 11, 2014
Received: April 14, 2014

Dear Mr. Parker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140179

Device Name
Precision Medical Easy Go Vac (PM66)

Indications for Use *(Describe)*
The Easy Go Vac Aspirator provides a portable, AC/DC powered medical vacuum source.
It is intended for use in the homecare / healthcare enviroments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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